April 2005

Idaho Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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Val D. Middleton

Val, a noted Southern Idaho pharmacist, passed away January 28, 2005. Val graduated from Idaho State University (ISU) College of Pharmacy in 1950. While at ISU he met and married his wife and partner of 55 years, Jean Munsee. After graduation Val worked in pharmacies in Rexburg and Idaho Falls. He retired in 1994 after 43 years as manager of Hyway Drug in Idaho Falls. Even in retirement he continued to work as a pharmacist at Don Wilson Drug and the Prescription Center until his final retirement in 1999. Val had an outstanding career in pharmacy. He was a member of the Idaho Board of Pharmacy for 10 years and was Board chairman twice during that time. He was a member of the Dean's Advisory Council for ISU's College of Pharmacy. He was past president of the Idaho State Pharmacist Association. He acted as a preceptor for many young pharmacy students.

In 2000, he was granted the ISU Professional Achievement Award by the College of Pharmacy. He was Pharmacist of the Year in 1985 and received special recognition in 2000 for 50 years of service to the pharmacy profession.

Val set an example for all of pharmacy with his unselfish time and energy he gave back to the profession and his patients during his long career.

License Renewals

Renewal season is rapidly approaching. License renewals will be mailed the last week in April. Renewals of pharmacists are mailed to their last known address. If you have had an address change you must notify the Board office. Any registrant who does not receive a renewal notice by the second week in May is advised to download one from www.state.id.us/bop/forms/index.html. Remember, it is your responsibility to renew your license prior to the expiration date of June 30 each year. Any renewal application postmarked July 1 or later will be assessed a $75 reinstatement fee. The most common problems we have when processing renewals are:

- Employment information incomplete;
- Address information not updated;
- Continuing education (CE) verification not complete; and
- Application not signed.

If your renewal application is not complete or does not contain the proper fee it will be returned unprocessed, which could result in a reinstatement fee.

Pharmacy Technicians Taking Verbal Prescription Orders

Over the past several months our compliance officers have issued several citations to pharmacy technicians for taking new prescriptions via the telephone from the practitioner or the practitioner's agent. Usually what happens is that the compliance officer or Board office will hear about a technician taking a prescription order from the nurse or the practitioner that gave the verbal order to the technician. Following a determination that the pharmacy technician has taken a verbal prescription from the practitioner or the practitioner's agent, both the pharmacy technician and the supervising pharmacist are issued citations. To prevent this type of problem with your pharmacy personnel please review the following information respective to what actions a registered pharmacist is required to perform in a licensed pharmacy.

Only a registered pharmacist may do any of the following:

1. Receive a new prescription order verbally from a prescriber or other person authorized by law.
2. Perform evaluations and interpretations of a prescription and any needed clarification prior to filling.
3. Consult with the prescriber concerning any necessary clarification regarding a patient and his prescription.
4. Interpret any clinical data in a patient's medication record system.
5. Perform professional consultation with any prescriber, nurse, or any health care professional.
6. Supervise the packaging of drugs and check the completed procedure and product.
7. Issue the new prescription to the patient or his or her agent with consultation.
8. Supervise the activities of pharmacy technicians to ensure that all such activities are performed completely, safely, and without risk or harm to patients.

The Board of Pharmacy may initiate proceedings against pharmacy technicians who perform such tasks or functions connected with the preparing, compounding, distribution, or dispensing of medications in a negligent or improper manner or that otherwise violate the rules on pharmacy technicians. Such violations may be grounds for revocation or suspension of the pharmacy technician's registration, or other appropriate disciplinary action.

In addition, a violation of the rules on pharmacy technicians will result in the supervising pharmacist being charged with unprofessional conduct, and is grounds for revocation or suspension of the pharmacist's license and/or the pharmacy registration, or other appropriate disciplinary action.

It would be a good idea if this information were provided to all pharmacists and pharmacy technicians for their review. A formal acknowledgement of the content (such as their signature acknowledging that they fully understand the content) would be a constructive way to assure that this does not become a problem in your pharmacy.

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HHS Provides Relief for Influenza Vaccine Shortage

To alleviate the influenza vaccine shortage, outgoing US Department of Health and Human Services (HHS) Secretary Tommy G.Thompson announced on December 7, 2004, that HHS purchased influenza vaccine (Fluarix®) from a German GlaxoSmithKline (GSK) facility under an Investigational New Drug (IND) application authorized by Food and Drug Administration (FDA).

In addition to conducting an inspection of the German GSK facility, FDA has reviewed extensive manufacturing and clinical information to determine and ensure the integrity of the vaccine and that it would be effective against the influenza strains dominant in the US during this flu season. With the IND, patients, prior to inoculation with the Fluarix vaccine, must sign an informed consent form that provides important information and an acknowledgement of the potential adverse effects associated with Fluarix. Sponsors of INDs are required to adhere to certain requirements such as maintaining adequate records, assuring that informed consent is obtained from individuals prior to vaccine administration, and providing periodic reports to FDA regarding safety and other issues.

In early October 2004, Chiron Corporation, one of two major pharmaceutical manufacturers of influenza vaccine, informed the Centers for Disease Control and Prevention (CDC) that it would be unable to distribute its estimated 48 million doses of Fluvirin® in time for the 2004-2005 flu season. The United Kingdom's Medicines and Healthcare products Regulatory Agency temporarily suspended Chiron's license for its Liverpool facility that was scheduled to produce Fluvirin for distribution throughout the US. Before Chiron's announcement, it was expected that 100 million doses would be available during this season, with Aventis, the other major influenza vaccine (Fluzone®) producer, contributing 54 million doses.

Individuals who are having difficulty finding the vaccine or who want additional information on influenza can call the CDC's hotline at 1-800/CDC-INFO.

FDA Urges Consumer Education About Counterfeit Drugs

In an interim report, FDA's Anti-Counterfeiting Task Force stressed the importance of increasing awareness and education of stakeholders, including the public, concerning counterfeit drugs. The report called for increasing efforts of FDA and other government agencies to educate consumers and health care professionals on how to reduce the risk of obtaining counterfeit drugs before the event occurs; educating consumers and health care professionals on how to identify counterfeit drugs; and improving and coordinating FDA and industry messages and efforts to address and contain a counterfeit event. At press time, FDA had available on its Web site (www.fda.gov/cder/consumerinfo/counterfeit_all_resources.htm) public service announcements that can be printed for consumers as well as educational articles to educate the public.

One recent high-profile case concerned Viagra® (sildenafil citrate) that were dispensed from two pharmacies located in California. The counterfeit product closely resembles genuine Viagra tablets with respect to size, shape, color, and imprinting; however, the counterfeit drugs have subtle differences in tablet edging, film coating, imprinting font, and packaging. At press time, FDA, along with Pfizer, Inc, the legitimate manufacturer of Viagra, was analyzing the counterfeit product to determine its true composition and whether or not it posed any health risks; fortunately, no injuries had been reported. Comparative photos of the counterfeit drug and genuine Viagra, refer to Pfizer's "Dear Pharmacist" letter posted on the company's Web site at www.pfizer.com, FDA's distributed a press release that is now available at www.fda.gov/.

Exactly one month after the counterfeit Viagra product was discovered, FDA expressed concern regarding counterfeit versions of the prescription drugs Zocor® (simvastatin) and carisoprodol, which were imported from Mexico by US citizens. Tests of these products revealed that the counterfeit Zocor, reportedly purchased at Mexican border-town pharmacies and sold under the name Zocor 40/mg (lot number K9784, expiration date November 2004, and lot number K9901, expiration date December 2006), did not contain any active ingredient. Likewise, the counterfeit carisoprodol 350/mg (lot number 68348A) test results indicated the products differed significantly in potency when compared to the authentic product. FDA continues to investigate this matter and is working with Mexican authorities to ensure that further sale and importation of these products are halted. For more information on counterfeit Zocor, visit www.fda.gov/bbs/topics/ANSWERS/2004/ANS01303.html.

Diabetes or Alzheimers?

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confi-

dentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Several reports of mix-ups have been reported in which the antidiabetic agent **AMARYL** (glimepiride) had been dispensed to geriatric patients instead of the Alzheimer's medication **REMINYL** (galantamine). Each drug is available in a 4 mg tablet, although other tablet strengths are also available for each.

In one case, a 78-year-old woman with a history of Alzheimer's disease was admitted to the hospital with hypoglycemia (blood glucose on admission 27 mg/dL). A review of the medications she was taking at home revealed that her pharmacist dispensed Amaryl 4 mg, which she took twice daily instead of Reminyl 4 mg BID. In another case, an 89-year-old female received Amaryl instead of Reminyl for three days, eventually requiring hospitalization for treatment of severe hypoglycemia. A third patient received Amaryl instead of Reminyl while in the hospital, leading to severe hypoglycemia. All patients recovered with treatment. These events have been linked to poor prescriber handwriting and sound-alike, look-alike names. It is possible that prescriptions for Amaryl are more commonly encountered than those for Reminyl. Thus, confirmation bias (seeing that which is most familiar, while overlooking any disconfirming evidence) may lead pharmacists or nurses into "automatically" believing a Reminyl prescription is for Amaryl.

Obviously, accidental administration of Amaryl poses great danger to any patient, especially an older patient, who may be more sensitive to its hypoglycemic effects. Practitioners should be alerted to the potential for confusion between Amaryl and Reminyl. Prescribers should be reminded to indicate the medication's purpose on prescriptions. Consider building alerts about potential confusion into computer order entry systems and/or adding reminder labels to pharmacy containers. Patients (or caregivers) should be educated about all of their medications, so they are familiar with each product's name, purpose, and expected appearance. Most importantly, at all times, pharmacists and nurses should confirm that patients are diabetic before dispensing or administering any antidiabetic medication, including Amaryl. FDA, Aventis (Amaryl), and Janssen (Reminyl) are aware of these reports and will be taking action to help reduce the potential for errors.

Medication Safety Videos Available for Free

The FDA Center for Devices and Radiological Health (CDRH) has been producing a monthly series of patient safety videos available via the Internet. ISMP and FDA's Division of Medication Errors and Technical Support, Office of Drug Safety, have been cooperating in this effort. Access www.ismp.org/Pages/FDAVideos.htm for videos related to medication errors. See www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/viewbroadcasts.cfm for a complete list of all broadcasts.

2005 Survey of Pharmacy Law Now Available

NABP's *2005 Survey of Pharmacy Law* CD-ROM is now available. Eight new questions were added to this year's *Survey*; topics include the formatting requirements of prescription pads, laws/regulations on the disposal of medications, and pharmacists allowed to dispense emergency contraception without a prescription.

The *Survey* can be obtained for $20 from NABP by downloading the publication order form from www.nabp.net and mailing in the form and money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from GlaxoSimthKline. If you do not have Web access or would like more information on the Survey, please contact NABP at 847/391-4406 or via e-mail at custserv@nabp.net.

NABP Headquarters Moves to New Location

NABP has moved its Headquarters to 1600 Feehanville Drive, Mount Prospect, IL 60056. The new phone number is 847/391-4406 and the new fax number is 847/391-4502. All printed communications can be sent to the Feehanville Drive address. If you have any questions concerning the Association's new Headquarters, please contact Customer Service at custserv@nabp.net or call 847/391-4406.

Register Now for NABP's 101st Annual Meeting

Register now for NABP's 101st Annual Meeting, May 21-24, 2005 at The Sheraton New Orleans Hotel, in New Orleans, LA, so you can take advantage of the chance to earn up to five hours of continuing education (CE).

This year, CE sessions will focus on topics that fall under the Meeting's theme, A Medley for Patient Safety: Accreditation, Self Assessment, Quality Care. Other events include the Educational Presentation Area and Poster Session, the President's Welcome Reception, NABP's Business Sessions, and the Annual Awards Dinner. In addition, you and your spouse or guest will have the opportunity to participate in a special recreational tour and the annual Fun Run/Walk.

For more information visit NABP's Web site at www.nabp.net or contact NABP by calling 847/391-4406 or e-mailing custserv@nabp.net.

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A technician may receive refill information from a practitioner's office as long as the verbal information being given to the pharmacy technician is just an informational statement such as, "It is okay to refill Mrs Johnson's furosemide prescription." If there are any changes to the original prescription such as the strength, quantity, directions, or practitioner name it immediately becomes a new prescription order and must be given to a pharmacist.

Compounding or Manufacturing

Compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available drug products would not be consistent with Food and Drug Administration's (FDA) Compliance Policy Guide (CPG). In certain circumstances it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available. However, in these circumstances FDA and the Board of Pharmacy would consider whether or not there was sufficient documentation of the medical need for the particular variation of the compound for that particular patient.

In the United States Pharmacopeia–National Formulary there is a section on pharmacy compounding. In that section the differences between compounding and manufacturing are discussed at some length. Some of the characteristics that differentiate compounding from manufacturing include the existence of specific practitioner-patient-pharmacist relationships, including the quantity of medication prepared in anticipation of receiving prescriptions and the conditions of sale, which are limited to patient-specific prescription orders. Both FDA and the Board of Pharmacy would consider a pharmacy to be manufacturing if the pharmacy were selling of compounded products to a practitioner for his or her own office use. A facility that acquires stock medications in this manner is considered to be receiving drugs from unlicensed or improperly licensed sources. For additional information on compounding, the CPG may be downloaded at www.fda.gov/cder/pharmcomp under "Guidance for Industry."

Nurse Practitioners and Physician Assistants in Idaho

Both nurse practitioners (NPs) and physician assistants (PAs) in Idaho have prescriptive authority from their individual licensing boards that gives them the authority to prescribe medications in Idaho including controlled substances. PAs are given prescriptive authority from the Board of Medicine and NPs receive their prescriptive authority from the Board of Nursing. To clarify this matter further, it means that if a pharmacy receives a written prescription for a controlled substance in Schedules II-V from either a PA or an NP in Idaho the prescription is valid as long as the practitioner has a current controlled substance registration and a current Drug Enforcement Administration (DEA) registration in Idaho. If the NP or PA is located outside of Idaho he or she would be treated the same way as any other out-of-state practitioner. If the prescription is written for a legend drug the pharmacist must verify that the practitioner has a valid medical license in the state in which the prescription was written and it is within the scope of his or her intended practice; if the prescription is for a controlled substance the pharmacist must also verify that the practitioner has a valid DEA registration in the state in which the prescription was written. Both NPs and PAs are also required to use the uncopyable prescription blanks for all controlled substance prescriptions written in Idaho. The only difference in the prescription blank requirements for a PA and an NP is that a PA is required to include the name of his or her supervising physician on all of his or her prescription blanks and an NP is not required to do so by his or her licensing Board.

Controlled Substance Prescriptions Written by Out of State Prescribers

Controlled substance prescriptions written by out-of-state practitioners are not required to be written on uncopyable paper in order to be considered valid. If a patient sees a doctor in Oregon and is given a prescription for a controlled substance and subsequently returns to Idaho to have the prescription filled, the prescription need not be written on uncopyable paper.

The *Idaho Board of Pharmacy News* is published by the Idaho Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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